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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/905,484	07/13/2001	Moncef Jendoubi	252/159	3711
34313	7590	03/18/2004	EXAMINER	
ORRICK, HERRINGTON & SUTCLIFFE, LLP 4 PARK PLAZA SUITE 1600 IRVINE, CA 92614-2558			COUNTS, GARY W	
			ART UNIT	PAPER NUMBER
			1641	

DATE MAILED: 03/18/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/905,484

Applicant(s)

JENDOUBI, MONCEF

Examiner

Gary W. Counts

Art Unit

1641

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 December 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-8 and 15-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8 and 15-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of the claims

The amendment filed December 15, 2003 is acknowledged and has been entered.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 1-8 and 15-20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 the recitation "wherein each area of the array is identified with" is vague and indefinite because it is unclear if each antibody binds to a polynucleotide sequence or if each antibody is linked to a polynucleotide sequence which hybridizes to another molecule or if the antibody is binding only to an antigen. Please clarify

Claim 15 the recitation "each area of the array is identified" is vague and indefinite. It is unclear what applicant intends by "identified". Does each antibody bind a protein or does the antibody bind to a polynucleotide sequence comprised by the protein. It is unclear what relationship exists between the antibody and the polynucleotide sequence.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the

applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

4. Claims 1-8, 15-18 and 20 are rejected under 35 U.S.C. 102(e) as being anticipated by Wagner et al (US 6,329,209).

Wagner et al disclose arrays of antibodies which are arranged in discrete, known regions on the portions of a substrate (solid support) surface and wherein each patch comprises antibodies attached thereon. Wagner et al disclose that the antibodies of a given patch are capable of binding a particular antigen and that the array comprises a plurality of different antibodies, each of which is capable of binding a particular antigen (col 2, line 63 – col 3, line 9). Wagner et al disclose that these antibodies may be polyclonal or monoclonal antibodies, or antibody fragments and that the antibodies can be IgG (col 13, lines 6-20). Wagner et al also disclose that the arrays comprise at least about 10 different antibodies and more preferably, at least about 100 different antibodies and may contain 10,000 different antibodies (col 11, lines 1-42). Wagner et al disclose that these antibodies can be derived from natural sources, or partly or wholly synthetically produced. Wagner et al disclose that the antibodies are derived from a mouse (col 26). Wagner et al disclose that the antibody can be isotypes (col. 5, line 56). Wagner et al disclose that the array can be used as a diagnostic tool in evaluating the status of a tumor or diseased tissue (columns 11, 37 and 38). Wagner et al also disclose using the array with a biochip to form a device (col 37, line 54-59).

With respect to the limitations of claim 5 directed to "obtained from immunization of a murine animal with the polynucleotide sequence encoding the antigen" has not

been given patentable weight because the claims are directed to a composition and a device and not a method. The limitations read as a requirement to an assay and therefore Wagner reads on instantly recited claim 5.

5. Claims 1 and 15 are rejected under 35 U.S.C. 102(e) as being anticipated by Chin et al (US 6,197,599).

Chin et al disclose a device comprising a solid support and multiple immobilized antibodies for protein detection. Chin et al disclose that the antibodies are individually deposited in a predetermined order, so that each of the agents can be identified by the specific position it occupies on the support. Chin et al disclose that the antibodies can be raised by immunizing animals such as a mouse.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claim 19 is rejected under 35 U.S.C. 103(a) as being unpatentable over Wagner et al (US 6,329,209).

See above for teachings of Wagner et al.

Wagner et al differ from the instant invention in failing to teach at least 10% of the reaction sites of the array are comprised of aliquots of homogenous antibodies.

With respect to at least 10% of the reactions sites of the array is comprised of aliquots of homogenous antibodies as recited in the instant claims, the optimum percentage of reaction

sites to determine an analyte of interest can be determined by routine experimentation and thus would have been obvious to one of ordinary skill in the art. Further, it has long been settled to be no more than routine experimentation for one of ordinary skill in the art to discover an optimum value of a result effective variable. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum of workable ranges by routine experimentation." Application of Aller, 220 F.2d 454,456, 105 USPQ 233, 235-236 (C.C.P.A. 1955). "No invention is involved in discovering optimum ranges of a process by routine experimentation ." Id. At 458,105 USPQ at 236-237. The "discovery of an optimum value of a result effective variable in a known process is ordinarily within the skill of the art." Application of Boesch, 617 F.2d 272,276, 205 USPQ 215, 218-219 (C.C.P.A. 1980).

Response to Arguments

8. Applicant's arguments filed December 15, 2003 have been fully considered but they are not persuasive.

Applicants argue that the amended claims specify a structural feature of the individual members of the array. This is not found persuasive because it is unclear if each antibody binds to a polynucleotide sequence or if each antibody is linked to a polynucleotide sequence which hybridizes to another molecule or if the antibody is binding only to an antigen. Further, it is unclear if each antibody bind a protein or does the antibody bind to a polynucleotide sequence comprised by the protein. It is also unclear what relationship exists between the antibody and the polynucleotide sequence. Applicant further argues that the arrangement of the array into areas that convey information about polynucleotides expressed to yield the antibodies confined at the

discrete areas of the array and thus a structural feature of the array provides information about the polynucleotide form the protein-antibody interaction. In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., convey information about polynucleotides expressed to yield the antibodies confined at the discrete areas of the array) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). The claims as recited merely reads on an array with 10 different antibodies. Wagner et al specifically discloses these limitations.

Applicant argues that Chin et al fail to teach a polynucleotide sequence and an antibody located at a discrete area on the array and that Chin fails to teach any feature that conveys information about a polynucleotide. This is not found persuasive because it is unclear what applicant intends by reciting "each area of the array is identified" (see above 112 rejections). The claims as recited merely reads on an array with 10 different antibodies. Chin et al specifically disclose these limitations.

Conclusion

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gary W. Counts whose telephone number is (571) 2720817. The examiner can normally be reached on M-F 8:00 - 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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Gary Counts

Examiner

Art Unit 1641

March 12, 2004



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03/12/04